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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/403,429 10/20/99

SHIMIZU

T 2535USOP

EXAMINER

TRAN, S

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

10/02/01

023115
TAKEDA PHARMACEUTICALS NORTH AMERICA, IN
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE IL 60069

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
09/403,429

Applicant(s)
Shimizu et al.

Examiner
Susan Tran

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 14, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 13-19 is/are pending in the application.
- 4a) Of the above, claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13, 18, and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of applicant's Preliminary Amendment A filed 10/20/99, Request to Withdraw Attorney filed 06/28/00, Amendment B filed 09/13/00, Amendment C filed 02/23/00, Request for Extension of Time filed 02/23/00, Request for Extension of Time filed 04/10/00, Request for Continued Examination filed 04/10/01, Declaration 1.132 filed 04/10/01, Preliminary Response filed 04/10/01, Amendment D filed 07/14/01, and Supplemental Information Disclosure Statement filed 07/14/01.

Response to Amendment

Newly submitted claims 14-17 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The original filed claims are directed to a solid preparation, e.g., tablet, and was classified in class 424, subclass 464. The amended claims are directed to an enteric-coated granule which is in class 424, subclass 490. The newly submitted claims would require further search.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 14-17 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Response to Arguments

1. Applicant's arguments filed 07/14/01 have been fully considered but they are not persuasive. The examiner maintains the original rejection and thus, claims 1-7, and 13-19 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ohno et al. US 5,958,453, in view of Shashoua et al. US 5,795,909.

The Declaration under 37 CFR 1.132 filed 04/10/01 has been considered but fails to overcome the rejection of claims 1-7, and 13-19 based upon the teaching of Ohno as set forth in the last Office action because:

The Declaration is directed to a production of an enteric coating granule, granules having a core, or mixed powder that are not claimed. The time obtained that is showed by the Declaration are within the ranges of the prior art, 0.1 to 1.0 second (column 6, lines 65-67). The term "[no] chalky taste" to "[a] little chalky taste" is too relative to allow scientific comparison. Furthermore, Ohno is also interested in hardness, as well as dissolution time of the tablet, therefore applicant fails to establish unexpected results over the teaching of Ohno. Accordingly, the Declaration does not establish superior results over the applied prior art.

Applicant argues that the Declaration disclosed Example A (applicant's invention) shows the average oral disintegration time was 29 seconds, while Example B (Ohno's invention) shows the disintegration time was 54 seconds. Thus, "they have presented evidence which is not merely indicative of rapid dissolution, but rather demonstrative of an unexpectedly far higher rate of dissolution that would have been anticipated, given the adjustment to the formulation made".

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Contrary to the applicant's argument, since Ohno teaches a buccal tablet that is completely dissolved within the ranges of about 6 seconds to 60 seconds (column 6, lines 62-67), it would have been obvious to one of the ordinary skill in this art to, by routine experimentation prepare formulations having "an unexpectedly far higher rate of dissolution". Hence, the Declaration does not establish any unexpected results over Ohno's invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600